

Complete Summary

GUIDELINE TITLE

The role of local vaginal estrogen for treatment of vaginal atrophy: 2007 position statement of The North American Menopause Society.

BIBLIOGRAPHIC SOURCE(S)

The North American Menopause Society. The role of local vaginal estrogen for treatment of vaginal atrophy in postmenopausal women: 2007 position statement of The North American Menopause Society. Menopause 2007 May-Jun;14(3 Pt 1):355-69; quiz 370-1. [84 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Vaginal atrophy in postmenopausal women

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Treatment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Oncology
Urology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Managed Care Organizations
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To create an evidence-based position statement published by The North American Menopause Society (NAMS) on the role of local vaginal estrogen therapy (ET) for the treatment of vaginal atrophy in postmenopausal women

TARGET POPULATION

Postmenopausal women

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

Pretreatment evaluation including comprehensive history and physical examination

Treatment

1. Nonhormonal vaginal lubricants and moisturizers
2. Local vaginal estrogen (estradiol vaginal cream, conjugated estrogens [CE] vaginal cream, estradiol vaginal ring, estradiol hemihydrate vaginal tablet)

MAJOR OUTCOMES CONSIDERED

- Symptom relief
- Quality of life
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For this position statement, The North American Menopause Society (NAMS) systematically reviewed the relevant medical literature. Using the MEDLINE database, a search was made for clinical trials, meta-analyses, and clinical practice guidelines published in English and related to vaginal ET for vaginal atrophy in postmenopausal women. The Medical Subject Headings used for the search were postmenopause, physiological sexual dysfunction (including dyspareunia, vaginismus, and vaginitis), and vaginal disease, with subheadings of epidemiology, etiology, diagnosis, prevention, control, and therapy. The National Guideline Clearinghouse was searched for relevant clinical practice guidelines, and the Cochrane Library was searched for relevant systematic reviews. Priority was given to evidence from randomized controlled clinical trials and to meta-analyses of such trials, followed by evidence from controlled observational studies, using criteria described elsewhere. Conclusions from other evidence-based guidelines were also reviewed. Because standards of care and treatment options differ throughout the world, the focus was limited to therapies available in North America.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In developing this position statement, The North American Menopause Society (NAMS) enlisted a five-person Editorial Board composed of experts in endocrinology, gynecology, and female genital diseases. The Editorial Board reviewed, synthesized, and interpreted the published data, developed conclusions, and made recommendations. If the evidence was contradictory or inadequate to form a conclusion, a consensus-based opinion was established. (Practice parameter standards related to NAMS position statements have been described in an editorial [see "Availability of Companion Documents" field in this summary]).

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This position statement was edited, modified, and subsequently approved by The North American Menopause Society (NAMS) Board of Trustees on February 23, 2007.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Summary

- The primary goals of vaginal atrophy management are to relieve symptoms and reverse atrophic anatomic changes.
- First-line therapies for women with vaginal atrophy include nonhormonal vaginal lubricants and moisturizers.
- For symptomatic vaginal atrophy that does not respond to nonhormonal vaginal lubricants and moisturizers, prescription therapy may be required.
- Randomized controlled trials in postmenopausal women, albeit limited, have shown that low-dose, local, prescription vaginal estrogen delivery is effective and well tolerated for treating vaginal atrophy while limiting systemic absorption.

- All low-dose vaginal estrogen products approved in the United States for treating vaginal atrophy (estradiol vaginal cream, conjugated estrogens (CE) vaginal cream, the estradiol vaginal ring, and the estradiol hemihydrate vaginal tablet) are equally effective at the doses recommended in labeling. The choice is dependent on clinical experience and patient preference.
- Progestogen is generally not indicated when low-dose estrogen is administered locally for vaginal atrophy.
- If a woman is at high risk for endometrial cancer, is using a greater dose of vaginal estrogen therapy (ET), or is having symptoms (spotting, breakthrough bleeding), closer surveillance may be required. There are insufficient data to recommend annual endometrial surveillance in asymptomatic women using vaginal ET.
- Vaginal ET should be continued as long as distressful symptoms remain.
- For women treated for non-hormone-dependent cancer, management of vaginal atrophy is similar to that for women without a cancer history. For women with a history of hormone-dependent cancer, management recommendations are dependent upon each woman's preference in consultation with her oncologist.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

The position statement was supported by evidence from randomized, controlled trials, meta-analyses, and review articles. If the evidence was contradictory or inadequate to form a conclusion, a consensus-based opinion was established.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of local vaginal estrogen therapy in the treatment and management of vaginal atrophy in postmenopausal women

POTENTIAL HARMS

- Adverse effects of local vaginal estrogen therapy (ET), including:
 - Vaginal bleeding and breast pain
 - Paresthesias and benign endometrial disorders
 - Candidiasis
 - Systemic absorption
 - Endometrial hyperplasia and adenocarcinoma

- If a woman is at high risk for endometrial cancer, is using a greater dose of vaginal ET, or is having symptoms (spotting, breakthrough bleeding), closer surveillance may be required.

QUALIFYING STATEMENTS

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Because standards of care and available treatment options differ throughout the world, the focus was limited to therapies available in North America.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Slide Presentation
Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

The North American Menopause Society. The role of local vaginal estrogen for treatment of vaginal atrophy in postmenopausal women: 2007 position statement of The North American Menopause Society. Menopause 2007 May-Jun;14(3 Pt 1):355-69; quiz 370-1. [84 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 May

GUIDELINE DEVELOPER(S)

The North American Menopause Society - Private Nonprofit Organization

SOURCE(S) OF FUNDING

The development of this position statement was supported by an unrestricted educational grant from Novo Nordisk, Inc.

GUIDELINE COMMITTEE

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For the Editorial Board, Dr. Bachmann reports: Research support: Berlex, Duramed, Johnson & Johnson, Pfizer, Roche, Wyeth; Speaker: Johnson & Johnson, Wyeth. Dr. Johnston reports: Advisory board: Paladin Labs Canada; Speaker: Paladin Labs Canada, Wyeth Canada. Dr. Kessel reports: Research support: Procter & Gamble, Wyeth; Speaker: Berlex, Merck, Procter & Gamble, Wyeth. Dr. Knobf reports: No significant financial relationships. Dr. Stewart reports: No significant financial relationships.

The NAMS Board of Trustees reports the following list of all financial relationships, not just those related to this CME activity: Dr. Clarkson reports: Member: Council on Hormone Education; Speaker: Wyeth. Dr. Freedman reports: Consultant: Alexza, Duramed, GlaxoSmithKline, Novartis, Organon, Pfizer, Vela, Wyeth; Research Support: GlaxoSmithKline, National Institutes of Health, Organon. Dr. Gallagher reports: Consultant, Research support: Organon, Pfizer, Wyeth. Dr. Goldstein reports: Advisory board: Eli Lilly, GlaxoSmithKline, Merck, Pfizer, Procter & Gamble. Dr. Gorodeski reports: Director, Medical Advisory Board: CytoCore. Dr. Henderson reports: Consultant: Council on Hormone Education, Wyeth. Dr. Kagan reports: Advisory board: Merck; Consultant: Merck, Roche/GlaxoSmithKline; Research support: Amgen, Aventis, Eli Lilly, Novartis, Procter & Gamble, Roche/GlaxoSmithKline, Wyeth; Speaker: Merck, Roche/GlaxoSmithKline. Dr. Pinkerton reports: Consultant: Boehringer Ingelheim, Duramed, Merck, Council on Hormone Education; Member: National Women's Health Resource Center; Research support: Solvay, Wyeth; Speaker: Merck. Dr. Reame reports: Consultant: Cypress Bioscience, Procter & Gamble; Research support: Novo Nordisk, Procter & Gamble. Dr. Rothert reports: No significant financial relationships. Dr. Schiff reports: Advisory board: *Pause*, the consumer magazine of the American College of Obstetricians and Gynecologists; Editor-in-chief: *Menopause*, the official journal of The North American Menopause Society. Dr. Speroff reports: Consultant: Warner-Chilcott; Research support: Barr, Berlex, Organon, Wyeth. Dr. Stuenkel reports: No significant financial relationships. Dr. Utian reports: Advisory board: Consultant: Barr/Duramed, Berlex, Depomed, Endoceutics, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Organon, Pfizer, Roche/GlaxoSmithKline; Research support: Amylin, Barr, Berlex, Bristol Myers Squibb, Duramed, Eli Lilly, Forest, Galen, GlaxoSmithKline, Johnson & Johnson, Neurocrine, Novartis, Novo Nordisk, Organon, Pfizer, Pharmacia, Procter & Gamble, Roche, Sepracor, Solvay, 3M, Wyeth, Yamanouchi

For additional contributors, Ms. Boggs, Dr. Graham, and Ms. Wisch all report no significant financial relationships.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from [The North American Menopause Society \(NAMS\) Web site](#).

Print copies: Available from NAMS, P.O. Box 94527, Cleveland, OH 44101, USA.
Order forms are available in Portable Document Format (PDF) from [The NAMS Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Key points: NAMS 2007 position statement on vaginal ET for vaginal atrophy. Slide set. Available from [The North American Menopause Society \(NAMS\) Web site](#).
- NAMS continuing medical education (CME) activities. Available from [The NAMS Web site](#).
- Boggs PP, Utian WH. The North American Menopause Society develops consensus opinions. Menopause 1998 Summer;5(2):67-8. Available from the [NAMS Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI Institute on June 28, 2007. The information was verified by the guideline developer on July 13, 2007.

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